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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,174	01/14/2004	Willi Kaiser	31-HL-5510(5024-00126)	4195

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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	PAPER NUMBER
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,174	KAISER ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/13/06 (Amendment)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,9-15 and 17-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,9-15 and 17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response

1. The Applicant amended at least the independent claims in the response filed 12/13/06 hence, the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 103

2. Claims 1-4, 6, 9-14 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (US 5876351) in view of DeLuca et al. (US 6238338) and further in view of Wang (US 5967994), known hence as Wang ('994).

Rohde teaches the monitoring of electrocardiograms using a portable modular diagnostic medical device comprising an electrocardiogram (ECG) cartridge (12) with an input terminal and leads, an instrument amplifier (62), an analog-to-digital converter (72), memory, and a screen (20). Waveforms from individual leads are viewed on the screen, and the output of the signal via the serial port permits the ECG signal to be sent via cable to a computer, the computer inherently having peripherals such as a printer and memory, the memory read as external memory. The functionality of the monitoring device can be expanded or potentially expanded, such as adding the detection of cyclic artifacts and the selection of a lead based on the lack of artifacts (abstract; col. 3 @ 1-7, 18-22; col. 4 @ 21-23, 38-55; col. 5 @ 5-11, 18-20, 35-37, 57-61; col. 5 @ 66 – col. 6 @ 14; col. 6 @ 43-47; col. 7 @ 30-38, 55-60; col. 8 @ 33-46; col. 9 @ 29-46; col. 13 @ 7-9, 20-32; col. 16 @ 31-37).

As discussed in the previous paragraph of this action, Rohde discloses the claimed invention except for the analog-to-digital converter being connected between the instrument amplifier and the analysis module.

DeLuca et al. teach bio-signal monitoring using a component arrangement of the analog-to-digital converter (57) being connected between the instrument amplifier (55) and the analysis module (58) for the purpose of processing the electrocardiogram signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an analog-to-digital converter connected between the instrument amplifier and the analysis module in the Rohde system in order to minimize the need to auto-scale the gain, and to process the input signal such that the processing results in a larger dynamic signal range important in sampling low level bio-signals contaminated with large artifacts (fig. 5; col. 3 @ 11-18, 31-38, 59-62; col. 4 @ 65 – col. 5 @ 2; col. 5 @ 48-53, 58-63).

As discussed in the previous three paragraphs, modified Rohde discloses the claimed invention except for a twelve lead ECG system (claims 6, 14, 23) and an analysis module including a processor and software to detect cyclic artifact and select a lead for analysis based on the lack of cyclic artifact (claims 1, 9, 17).

Wang ('994) teaches signal characterization using a twelve lead ECG system and an analysis module, including a processor and software, to detect cyclic artifact and to select a lead for analysis based on the lack of cyclic artifact for the purpose providing the optimum lead configuration for an ECG study and for the purpose of determining the signal quality of the lead(s) sensing the ECG signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a twelve lead ECG system, and an analysis module,

including a processor and software to detect cyclic artifact, and to have selected a lead for analysis based on the lack of cyclic artifact in the modified Rohde system in order to provide a high quality, comprehensive ECG signal that, based on analysis, will have minimal distortion enabling the physician to make an accurate diagnosis (fig. 6,9; col. 1 @ 8-15; col. 2 @ 40-56; col. 3 @ 37 – col. 4 @ 11; col. 4 @ 19-34, 48-57; col. 5 @ 3-17; col. 6 @ 29-36; col. 13 @ 21-25; col. 16 @ 4-16).

The Applicant's arguments filed 12/13/06 have been fully considered, but they are not convincing.

The Applicant argues the Rohde device potentially cannot perform the detection of cyclic artifact and lead selection since the current electrocardiogram application is not as complicated as a cyclic artifact/ lead selection application. The Examiner disagrees.

Rohde teaches expanding the functionality of the medical device (col. 3 @ 1-7, 18-22; col. 4 @ 21-23; col. 16 @ 32-37) to include different diagnostic medical functionality, read to be detection of cyclic artifacts and the selection of a lead based on the lack of artifacts. Rohde teaches different medical functionality is achieved by the device when different cartridges are inserted into the device (col.3 @ 18-20; col. 4@ 21-23, 30-34, 45-52; col. 16 @ 31-36).

Rodhe teaches the medical device has 256 kilobytes available in the 27C256 EPROM for the use by the cartridge. The electrocardiogram application taught by Rohde uses less than 5 kilobytes to control:

1) monitoring electrocardiograms (ECGs) of the patient on three different leads, the monitoring including sampling/ measurement of the ECG signals, analog/ digital conversion of the signal and interface with the read-only memory,

2) displaying the actual scrolling of the ECGs on the device screen,

3) calibrating of the ECG amplitude,

4) audio output of the ECG signals,

5) sending the ECG data via modem,

6) labeling ECG waveforms with information, and

7) entering text information into memory.

Given the amount controlled by less than 5 kilobytes of the EPROM, it is accepted the 256 kilobytes available in the 27C256 EPROM for the use by the cartridge would be adequate to support a cartridge to detect cyclic artifacts and select a lead based on the lack of artifacts. Even if more memory was required, Rohde teaches the EPROM can be expanded by bank switching (col. 4 @ 46-48; col. 5 @ 57-59; col. 6 @ 17-27, 28-51, 59-62; col. 7 @ 1-5, 22-29; col. 13 @ 7-9, 20-34).

Based on the rejection of record and the discussion above, the claims stand rejected.

3. Claims 7, 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (US 5876351) and DeLuca et al. (US 6238338) and Wang (US 5967994), known hence as Wang ('994), and further in view of Wang (US 6119035), hence known as Wang ('035). As discussed in paragraph 2 of this action, modified Rohde discloses the claimed invention except for the multi-lead electrocardiogram (ECG) with five (claims 15, 24) or seven leads (claim 7).

Wang ('035) teaches synthesizing an ECG using a multi-lead ECG comprising five leads or seven leads for the purpose of synthesizing a twelve lead electrocardiogram. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the multi-lead ECG comprising five leads or seven leads in the modified Rohde system in order to quickly and easily produce a user acceptable synthesized twelve lead ECG, the result of the synthesis being easily check by adding one or more other leads, the synthesized twelve lead ECG reducing the number of leads required for the ECG, hence avoiding the accurate preparation and placement of ten electrodes require for the twelve lead ECG, and reducing the significant clutter that arises from the wires and connects associated with each electrode (abstract; col. 3 @ 12-30; col. 4 @ 47-51; col. 6 @ 12-36, 44-53; col. 7 @ 15-31).

Statutory Basis

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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FPO
1/5/07

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